

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:7283
ANSWERED ON:15.05.2002
LICENCE FOR IMPORT OF MEDICINES
PUNNULAL MOHALE

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether Government have made it mandatory to get a licence for import of medicines; and
- (b) if so, the details thereof?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) Yes, Sir.

(b) An Import Licence in Form 10 or Form 10-A is required for the import of a drug specified in Schedule 'C' & 'C1' or Schedule X as the case may be. For such an Import Licence an importer has to apply to the Licensing Authority in Form 8 or Form 8-A mentioning the name of drug to be imported along with prescribed fee and an undertaking in Form 9 duly signed by or on behalf of the manufacturer. If the applicant satisfies the conditions for the issue of said Import Licences by providing suitable storage premises, valid sale licences manufacturing licences issued under the provisions of Drugs and Cosmetics Rules, Import Licence in Form 10 or Form 10-A is issued to him. Recently, vide GSR No. 604(e) dated 24.8.2001 Government of India has made it mandatory that from 1.1.2003 Import Licence in Form 10 shall be required for all categories of drugs. For such an Import Licence, the importers shall have to apply in the same manner as stated above along with a copy of Registration Certificate specifically issued to the concerned foreign manufacturer of the drugs. If the importer could satisfy the conditions for import of drug as mentioned above. Import Licence in Form 10 or Form 10-A shall be issued to him. An application for issue of a Registration Certificate shall be made in Form 40 by an Indian Authorized Agent of the foreign manufacturer who shall have a valid sale manufacturing licence. The application shall accompany with the prescribed fees and requisite information specified in Schedules D-I & D-II of the Drugs and Cosmetics Rules. If the foreign manufacturer would follow the conditions of the Registration Certificate by fulfilling the Good Manufacturing Practices and labelling conditions prescribed for the purpose. Registration Certificate in Form 41 shall be issued to the foreign manufacturer.